

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
7500 Standish Place (HFV-210)  
Rockville, MD 20855

**VETERINARY ADVERSE DRUG REACTION,  
LACK OF EFFECTIVENESS,  
PRODUCT DEFECT REPORT**

Form Approved: OMB No. 0910-0012  
Expiration Date: January 31, 1997

(Forward to address at left. Attach all correspondence that pertains to this reaction)

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS  
Hubert H. Humphrey Building, Room 721-B  
200 Independence Avenue, S.W.  
Washington, DC 20201 Attn.: PRA

and to

Office of Management and Budget  
Paperwork Reduction Project (0910-0012)  
Washington, DC 20503

**Please DO NOT return  
this report to either of  
these addresses.**

**NOTE: This report is required by law (21 CFR 510.300). Failure to report can result in withdrawal of approval of the application.**

1. REPORT SOURCE AND ADDRESS (Mfr., Distr.)		2. DATE SENT TO FDA (Month, day, year)	3. TYPE OF REPORT <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOW UP TO REPORT OF (Give Date)
4. NAME, ADDRESS AND PHONE NO. OF ATTENDING VETERINARIAN (In confidence)  ( ) - - - - -		5. NAME OR CASE IDENTIFICATION OF OWNER (In confidence)	
6. TRADE NAME AND GENERIC NAME(S) OF ACTIVE INGREDIENT(S) (Include dosage form and strength - Ex., tab, 500 mg.)		7a. NAME OF MANUFACTURER	
		b. NADA NO.	
8. LOT NUMBER	9. DOSAGE ADMINISTERED AND ROUTE (Ex. 250 mg., q 12 h, p.o.)	10. DATE(S) OF ADMINISTRATION	
11. ILLNESS/REASON FOR USE OF THIS DRUG		12. DRUG WAS ADMINISTERED BY <input type="checkbox"/> VETERINARIAN, STAFF <input type="checkbox"/> OWNER, OTHER	
13. NUMBER OF ANIMALS IN THIS INCIDENT		14. REACTING ANIMALS	
a. TREATED WITH DRUG	b. REACTED	c. DIED	a. SPECIES
			b. BREED
15. CONCOMITANT MEDICAL PROBLEMS			c. AGE
			d. WEIGHT
			e. SEX <input type="checkbox"/> FEMALE <input type="checkbox"/> MALE <input type="checkbox"/> PREGNANT <input type="checkbox"/> NEUTERED
16. OVERALL STATE OF HEALTH AT TIME OF REACTION <input type="checkbox"/> GOOD <input type="checkbox"/> FAIR <input type="checkbox"/> POOR <input type="checkbox"/> CRITICAL		17. DID ANY NEW ILLNESS DEVELOP OR DID INITIAL DIAGNOSIS CHANGE AFTER SUSPECT DRUG STARTED? <input type="checkbox"/> NO <input type="checkbox"/> YES (Explain)	
18. CONCOMITANT DRUGS ADMINISTERED			
NAME OF DRUG	ROUTE	DOSAGE REGIMEN	DATE(S) OF ADMINISTRATION

**FOR FDA USE ONLY**

1. _____	<input type="checkbox"/> D	<input type="checkbox"/> NAI
2. _____	<input type="checkbox"/> PR	<input type="checkbox"/> AI
3. _____	<input type="checkbox"/> PO	<input type="checkbox"/> AP
4. _____	<input type="checkbox"/> R	<input type="checkbox"/> AL
5. _____	<input type="checkbox"/> NC	
6. _____		
T. _____		
<input type="checkbox"/> I.L.	<input type="checkbox"/> CR	<input type="checkbox"/> CONT

**COMMENT**

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1. <input type="checkbox"/> D <input type="checkbox"/> NAI 2. <input type="checkbox"/> PR <input type="checkbox"/> AI 3. <input type="checkbox"/> PO <input type="checkbox"/> AP 4. <input type="checkbox"/> R <input type="checkbox"/> AL 5. <input type="checkbox"/> NC 6. <input type="checkbox"/> I.L. <input type="checkbox"/> CR <input type="checkbox"/> CONT T. <input type="checkbox"/>	COMMENT
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